FORM PTO-1390 (REV. 9-2001) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY 'S DOCKET NUMBER	
14185	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5	
NA 10/009319	
INTERNATIONAL APPLICATION NO. PCT/CH00/00241	INTERNATIONAL FILING DATE 01 May 2000
PRIORITY DATE CLAIMED 14 May 1999	

TITLE OF INVENTION CANNULA/NEEDLE COMBINATION FOR SUBCUTANEOUS ADMINISTRATION OF A SUBSTANCE

APPLICANT(S) FOR DO/EO/US
KIRCHHOFER, Fritz and STECH, Jurg

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [ ] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is attached hereto (required only if not communicated by the International Bureau).
   b. [ ] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [X] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [X] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [X] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [X] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [X] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [X] Other items or information: Submission under 37 C.F.R 3.73(b);
    Verification of Translation; and
    a Return Postcard

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
NA 10/009319	PCT/CH00/00241	14158

21. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):	CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890.00
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	9 - 20 =	0	x **$18.00**	$
Independent claims	1 - 3 =	0	x **$84.00**	$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$280.00**	$

TOTAL OF ABOVE CALCULATIONS =	$ 890.00
[ ] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. +	$
SUBTOTAL =	$ 890.00
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).	$
TOTAL NATIONAL FEE =	$ 890.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +	$ 40.00
TOTAL FEES ENCLOSED =	$ 930.00
Amount to be refunded:	$
charged:	$

a. [X] A check in the amount of $ 930.00 to cover the above fees is enclosed.

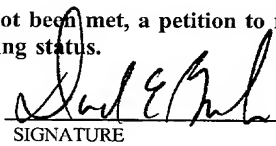
b. [ ] Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-1420 . A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:



SIGNATURE

David E. Bruhn

NAME

36,762

REGISTRATION NUMBER

5/PRTS

Cannula / Needle Combination for Subcutaneous Administration of an Active Substance

The invention relates to a cannula/needle combination for subcutaneous administration of an active substance, more particularly a medicinal active substance such as, for example, insulin. The cannula/needle combination is inserted into the skin or subcutaneously, and is, preferably, a cannula/needle combination of a catheter head.

A catheter head including a cannula like that concerned in the invention is known from DE 198 21 723. The catheter head comprises a cannula housing including the cannula and a needle mount to be connected to the cannula housing, the needle mount including a means for delivering the active substance. The cannula protrudes from the cannula housing and is placed in the tissue or subcutaneously. The cannula may be configured integrally with the cannula housing or be secured/anchored to the cannula housing, it being configured pliant, more particularly flexible. Configured in the cannula housing for the active substance is a communicating passage to the cannula. The cannula housing is formed so that it can be surface-mounted on the tissue the cannula is placed into, it being suitably prepared for fixing or securing to the tissue.

A catheter for delivering the active substance can be connected to the cannula housing by means of a needle mount. A connecting needle is rigidly secured to the needle mount which is inserted to create the connection in the communicating passage of the cannula housing. The cannula and cannula housing remain fixed in place in and on the tissue while the needle mount is repeatedly connected to/removed from the cannula housing.

Placing of the cannula into the tissue or subcutaneously occurs by means of a piercing needle. The piercing needle protrudes through the cannula housing and, in particular, the cannula. The cannula is a snug fit on the injection needle. After the piercing needle together with the cannula has been inserted into the skin or subcutaneously and the

cannula is thereby positioned at the desired penetration depth in the tissue, the piercing needle is removed from the cannula and cannula housing. Depending on the type of catheter head employed, the connecting needle is either already located in the communicating passage or is now introduced into the communicating passage to form the connection between the cannula housing and the needle mount and, thus, also the connection of the connecting needle to the cannula positioned in the tissue or subcutaneously.

To ensure that no air is conveyed through the cannula in subsequent administration of the active substance, a so-called priming, by means of which the cavities of the catheter head are pre-filled with the active substance, the cavities later guiding the active substance during administration, is carried out prior to insertion of the piercing needle and placing of the cannula. More particularly, pre-filling is carried out with the active substance being up to the tip of the piercing needle. For this purpose, the hollow piercing needle is provided with an opening at a suitable location in an area not protruding into the cannula, through which the active substance penetrates to reach the tip of the piercing needle during priming.

For the user it is evident that the catheter head is filled up to the tip of the injection needle with the medicament as soon as the medicament drips from the needle. Subsequent to this, the needle including the cannula is inserted in the skin or subcutaneously and the catheter head is placed on the skin. When the patient removes the needle from the catheter head after positioning, only the cannula remains in the tissue or subcutaneously.

One disadvantage of the needles known in the prior art is that the opening diminishes the stability of the needle, thus possibly resulting in kinking of the needle. This risk increases when very thin needles are employed, for example size 28G or thinner. The stability is always a problem where thin needles are concerned, even without additional weakening due to a possible opening. However, the thinner the needle and the cannula, the less unpleasant is the piercing experienced by the user.

An object of the invention is to provide a cannula/needle combination for an insertion into the skin or subcutaneously which may be thin and yet still comprises an enhanced resistance to kinking. Preferably, the combination is simple to handle and cost-effective to produce.

This object is achieved by the subject matter of claim 1. Preferred embodiments read from the features of the sub-claims.

The invention relates to a cannula/needle combination for subcutaneous administration of an active substance, in particular a medicinal active substance such as, for example, insulin. The combination comprises an injection needle and a cannula surrounding the injection needle which is snugly fitted to the injection needle.

In accordance with the invention the inner cross-section of the cannula and the outer cross-section of the needle in the combination differ, i.e. at least as regards the needle introduced into the cannula. The cross-sectional shape of the needle and the cross-sectional shape of the hollow cross-section of the cannula differ in such a manner that between the needle and the inner wall of the cannula a space remains through which active substance can be delivered. Accordingly, unlike the combination in accordance with the prior art, the cannula is now no longer a snug fit over the full circumference of the needle, but only in certain areas. Despite the needle being introduced, sufficient space remains within the hollow cross-section of the cannula through which the active substance can be delivered, it being more particularly through this cavity that the active substance is delivered during priming to then emerge from the frontal edge of the cannula.

In a preferred embodiment, the needle has an outer cross-section other than circular, while the inner cross-section of the cannula is circular, as is the case with conventional cannulas, so that between the inner cross-section of the cannula and the outer cross-section of the needle a space remains through which the active substance can run to the end of the cannula during priming.

Instead of using a needle having a non-circular cross-section in combination with a cannula having a circular cross-section, a needle having a circular cross-section may be combined with a cannula comprising a non-circular cross-section.

Both the needle and the cannula may each comprise an outer cross-section and inner cross-section respectively which is non-circular. Thus, for example, both cross-sections may be longer in one direction of their cross-section than in the other direction. It then needs to be assured, however, in the cannula/needle combination that sufficient space still remains for communicating the active substance. This is achievable more particularly by the longitudinal axis of the outer cross-section of the needle not coinciding with the longitudinal axis of the inner cross-section of the cannula; preferably, the two longitudinal axes are at a right angle of approximately 90° to each other. The inner cross-section of the cannula and/or the outer cross-section of the needle may be oval, for example, elliptical.

As an alternative to or in assisting such cannula/needle combinations the needle or the cannula, or both the needle and the cannula, may be provided with a longitudinally extending groove, indentation or notch or be configured flattened so that between the inner wall of the needle and cannula space remains for passage of the active substance to the tip of the cannula. Also, several grooves, or indentations, notches, or flattenings, or a culmination of several such forms, may be distributed at the respective circumference to facilitate passage.

It is not necessary that the outer cross-section of the needle, which differs from the inner cross-section of the cannula in forming the space, extends over the full length of the needle, although this is preferred for several reasons not least of which is that it permits a simple manufacture.

One very special advantage afforded by the invention is that the needle does not necessarily need to be hollow since the active substance is communicated between the outer cross-section of the needle and the inner cross-section of the cannula. However

even when using a hollow needle in the combination in accordance with the invention, a significantly higher kinking stability is assured in any case since providing the hollow needle with an opening is now eliminated. This opening is a mandatory requirement with the hollow needles in accordance with the prior art, however, to permit during priming transport of the active substance up to the tip of the cannula.

Further features and advantages of the invention read from the description of preferred example embodiments with reference to the attached drawings in which:

Fig.1 is a three-dimensional view of a catheter head including a cannula/needle combination,

Figs. 2a-2c are cross-sections through embodiments of cannula/needle combinations having non-circular needle outer cross-sections,

Figs. 3a-3c are cross-sections through embodiments of cannula/needle combinations having non-circular cannula inner cross-sections,

Fig. 4 is a longitudinal section through the catheter head in accordance with Fig. 1, and

Fig. 5 is a longitudinal section through a second example embodiment of a catheter head.

Referring now to Fig. 1, there is illustrated a catheter head including a cannula 1 protruding perpendicular from the underside of the catheter head. The cannula 1 is made of a soft plastics material, in the case of the example embodiment Teflon, it tightly surrounding a piercing needle N penetrating the catheter head perpendicular to the flat underside thereof. The piercing needle N with the surrounding cannula 1, which is preferably slightly expanded cross-sectionally by the piercing needle N and thus tensioned, will also be termed cannula/needle combination in the following. The catheter

head forms the frontal end of a catheter 5. The catheter 5 including the catheter head is positioned by a user himself, for example a diabetic. For this purpose, the piercing needle N and the cannula 1 are inserted vertically into the tissue under the skin or subcutaneously and the catheter head is fixed in place or secured with its underside lying two-dimensionally on the skin. Fixing occurs by means of a self-adhesive pad or sticky plaster. Such a pad enlarges the underside of the catheter head available for adhesive purposes. If this underside already has a sufficiently large adhesive surface area, then the configuration of this underside suffices as the adhesive surface area. Subsequent to placing of the cannula 1, the piercing needle N is removed from the catheter head so that only the thin, pliant, in particular, flexible cannula 1 remains in the tissue.

The catheter head comprises a cannula housing 2 which remains along with the cannula 1 at the piercing location and which comprises an underside serving to fix the catheter head in place. Furthermore, the catheter head comprises a needle mount 3 forming the frontal end of the catheter 5. The cannula housing 2 and the needle mount 3 constitute together a repeat make/break connection.

Common to all cannula/needle combinations shown in the drawings is that the needle N of each combination is configured as a non-hollow needle, wherein the inner cross-section of the cannula 1 and the outer cross-section of the needle N in cross-section form and/or in cross-section surface area deviate from each other so that one or more intermediate spaces remain for passage of an active substance, in particular for a priming. In the cannula/needle combination during priming the flow of the active substance is not within the needle, but along the outer shell surface area of the needle, i.e. in the space formed between the solid needle and the inner cross-section of the cannula to the tip of the cannula.

Figs. 2a to 2c illustrate cross-sections through various embodiments of combinations of cannulas 1 and needles N as may find application in the catheter heads shown in the drawings, however, may also be used in other catheter heads or even without a catheter head.

Referring now to Fig. 2a, there is illustrated an embodiment in which the needle N has an oval cross-section, whereas the inner cross-section of the cannula 1, prior to introduction of the needle N, is circular so that, after introduction, two spaces 24 remain between the inner cross-section of the cannula 1 and the outer cross-section of the needle N.

In the embodiment shown in Figure 2b, the needle N is provided with longitudinally extending straight grooves or indentations 26, the inner cross-section of the cannula 1 being circular as before. The grooves 26 of the needle N form together with the inner wall of the cannula 1 the cavity or cavities 24 for guiding the active substance.

In the embodiment illustrated in Figure 2c, the needle N comprises flats 28. This needle has an angled cross-section with chamfered edges, while the inner cross-section of the cannula 1, prior to introduction of the needle N, is round, indeed even circular prior to introduction of the needle. The active substance space 24 is thus formed in this embodiment by the flat flanks of the needle N and the inner wall of the cannula 1.

Secure seating of the needle N in the cannula 1 is achieved in all embodiments by the compression the cannula 1 experiences at the contact surface areas with the needle N.

Figs. 3a to 3c show alternative embodiments of cannula/needle combinations in accordance with the invention combining a solid needle N each having a circular cross-section with a cannula 1 comprising a non-circular inner cross-section. The inner cross-section of the cannula 1 in this arrangement may be oval, for example, elliptical, as shown in Fig. 3a. It may be provided with longitudinally extending grooves 28, as shown in Fig. 3b, or configured with flats, as shown in Fig. 3c, so that cavities 24 for passage of the active substance to the tip of the cannula 1 exist between the needle N and cannula inner wall in each case.

In addition to the embodiments as shown, also a combination of the individual features of the illustrated embodiments is possible, for example, two oval cross-sections.

Figs. 1, 4 and 5 represent a preferred application of the cannula/needle combination, namely in a catheter head.

Referring now to Fig. 4, it is illustrated how the active substance is delivered through the catheter 5 to the needle mount 3, it being directed through a connecting needle 4 mounted in the needle mount 3 into a communicating passage in the cannula housing 2. From here, it is further transported to the cannula 1 and gains access through the cannula 1 to the desired location in the tissue. An inlet and an adjoining portion of the communicating passage of the cannula housing 2 are surrounded by a cylindrical protuberance 6 protruding from a rear side of the cannula housing 2.

In the combined condition, the catheter head shown has, in all, the shape of a semi-ovaloid with a flat underside 12 rounded down to the edge from the skin and verging in the cannula housing 2 into an upper side curved thereabove partly convex and partly concave. The cannula housing 2 at which the underside 12, lying on the skin, is configured, comprises a rear discoid portion 11 and opposite thereto a thickened front portion 10, from the underside 12 of which the cannula 1 protrudes and from the rear side of which the cylindrical protuberance 6 and the discoid portion 11, shadowing the former, protrude backwards in the direction of the needle mount 3 which has to be directed there-against. The needle mount 3 is symmetrical in shape, i.e. its upper side and its underside are curved outwards in the same manner; furthermore, the needle mount is symmetrical in the top view with respect to its middle longitudinal axis.

The cylindrical protuberance 6 serves in cooperation with a guide sleeve 7, configured at the needle mount 3, as a guiding means for positioning the connecting needle 4 relative to the inlet 9 and for correct straight guidance of the connecting needle 4 in the portion of the communicating passage adjoining the inlet. This results in a part of the cannula housing 2, surrounding the communicating passage, being brought out from the cannula housing 2 in the form of the cylindrical protuberance 6 and can thus be used as the guiding means when inserting the connecting needle 4. The resulting cooperating guiding means at the needle mount 3 is formed by the guide sleeve 7 which, in addition to its

function as a guiding means, simultaneously protects the connecting needle 4, accommodated therein co-axially, from damage; moreover it protects the user from injury due to an exposed needle, for instance, caused by touch or careless handling. The guide sleeve 7 protrudes longitudinally beyond the connecting needle 4.

In the illustration of Fig. 4, the guide sleeve 7 is fully slid onto the cylindrical protuberance 6 and with its front edge abuts against the rear side of the cannula housing 2, from which the cylindrical protuberance 6 protrudes. In this condition, snap-action fingers grip behind corresponding protuberances provided in guide chutes, rendering any accidental release of the needle mount 3 impossible.

The connecting needle 4 pierces a septum 8 arranged directly behind the inlet in the communicating passage of the cylindrical protuberance 6. The septum 8 is configured so that even after it has been pierced several times it still provides a hermetic seal of the communicating passage of the cannula housing 2. Directly behind the septum 8, the communicating passage comprises a dome 18 into which the connecting needle 4 protrudes. Connected to the dome 18 is a passage section 19 running in a straight line in alignment to the connecting needle 4 and porting into a cavity 20 in the front portion 10 of the cannula housing 2. The cannula 1 also ports into this cavity 20. The piercing needle N is guided through the cavity 20 at an angle, in the example embodiment at right angles, to the connecting needle 4 and the passage section 19. The piercing needle N protrudes through the cannula housing 2 and is oriented at an angle, in the example embodiment at right angles, to the underside 12 of the cannula housing 2. In this arrangement, the piercing needle N is advantageously not guided through the part of the communicating passage of the cannula housing 2 into which the connecting needle 4 is introduced.

Due to this arrangement, there is no need to first remove the piercing needle N to permit introducing the connecting needle into the catheter head which is particularly of advantage in priming, in which the catheter head is to be filled as completely as possible with active substance before placing of the cannula 1.

The cannula 1 is configured as a thin tube with a flange-type widening 21 at one end. This flange-type widening 21 is received in a ringed discoid recess in the cannula housing 2 to thereby anchor the cannula 1.

Inset in the cavity 20, opposite the cannula inlet, is a further septum 22 which seals off the cavity 20, which is part of the communicating passage of the cannula housing 2, after removal of the piercing needle N. The function of the septum 22 is comparable to that of the septum 8. The shape of the cavity 20 is substantially cylindrical, the flange-type widening 21 of the cannula 1 and the septum 22 forming the opposite faces of the cylindrical cavity 20 and between which the passage section 19 ports.

Fig. 5 illustrates a modified example embodiment in which the piercing needle is inserted through the same communicating passage of the cannula housing 2 into which the connecting needle 4 is introduced after placing of the cannula 1. With the exception of this arrangement of the injection needle and cannula 1, the catheter head shown in Fig. 5 corresponds to that described above, to which reference is made accordingly.

What is claimed is:

1. A cannula/needle combination for subcutaneous administration of an active substance, more particularly a medicinal active substance such as, for example, insulin, said combination comprising

a) an injection needle (N) and

b) a cannula (1) surrounding said injection needle (N)
in a snug fit

characterized in that

c) the inner cross-section of said cannula (1) and the outer cross-section of said needle (N) differ from each other such that configured between them is at least one cavity (24) for passing through said active substance.

2. The cannula/needle combination as set forth in claim 1, characterized in that said needle (N) has a cross-section other than circular.

3. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said needle (N) is provided with at least one longitudinally extending groove, indentation or notch (26).

4. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said needle (N) is provided with at least one longitudinally extending flat (25).

5. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said cannula (1) comprises a cross-section other than circular.

6. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said inner cross-section of said cannula (1) is oval.

7. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said inner cross-section of said cannula (1) is provided with at least one longitudinal groove, indentation or notch (28) extending to an end of said cannula (1).

8. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said inner cross-section of said cannula (1) is provided with at least one longitudinally extending flat (28).

9. The cannula/needle combination as set forth in any of the preceding claims, characterized in that said needle (N) of said combination is configured as a non-hollow needle.

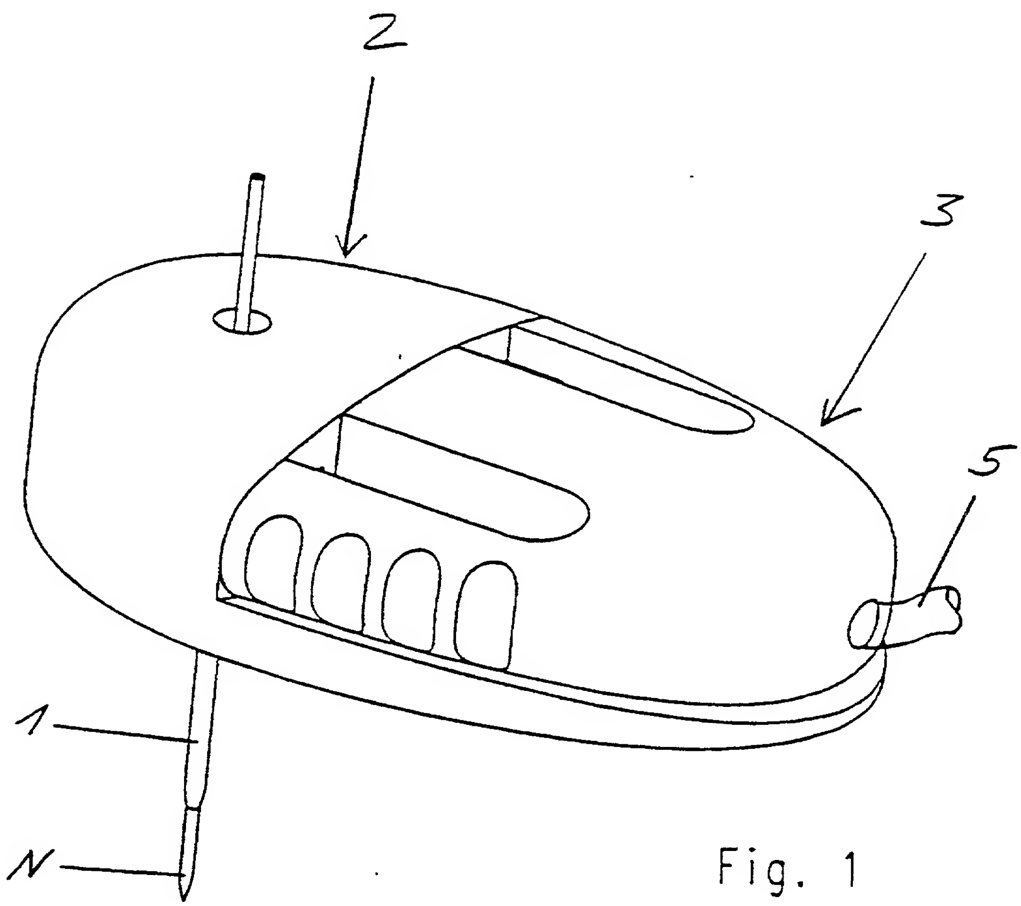


Fig. 1

Fig. 2a

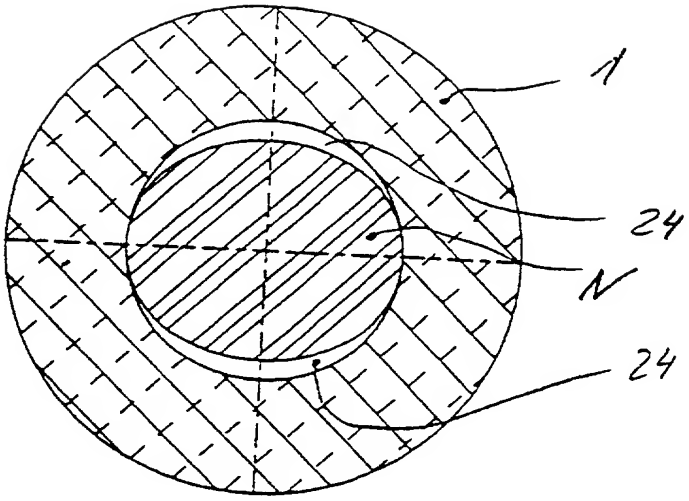


Fig. 2b

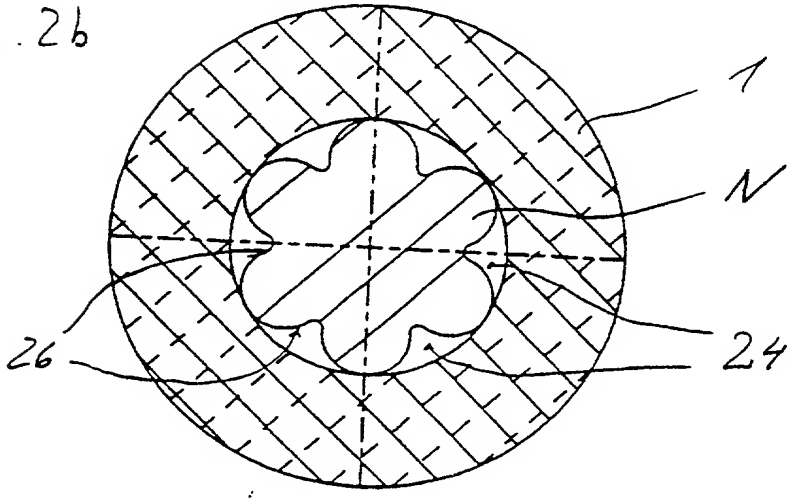


Fig. 2c

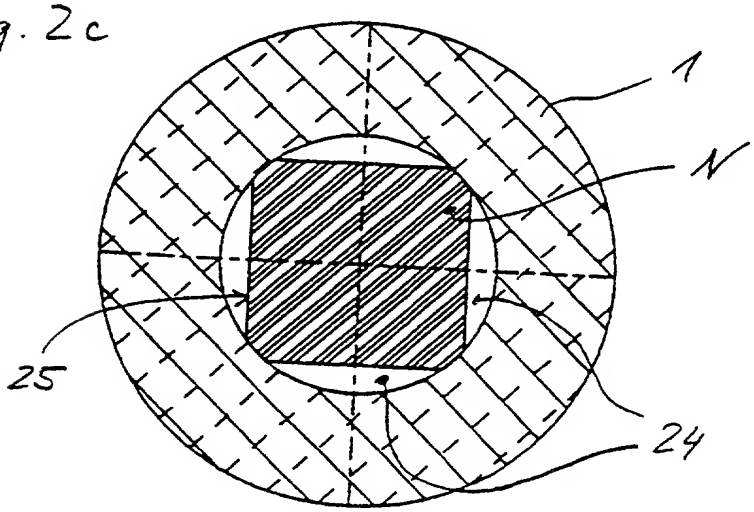


Fig. 3a

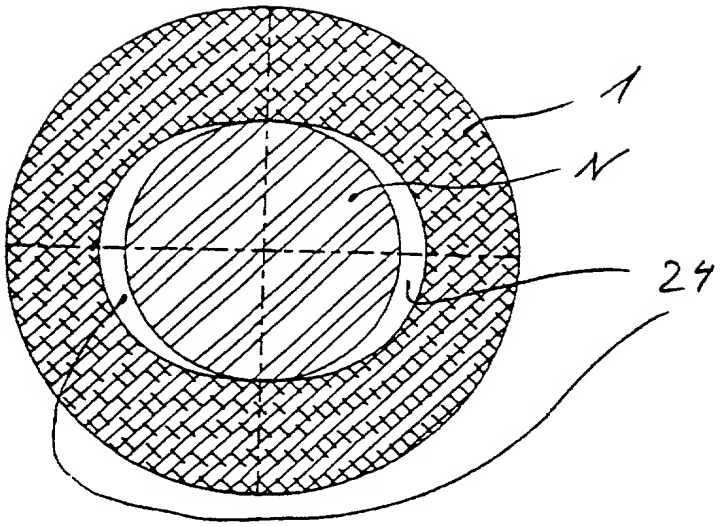


Fig. 3b

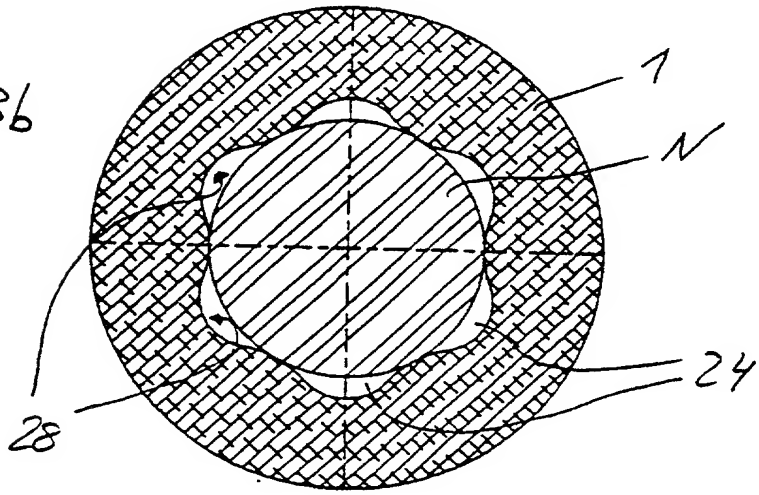
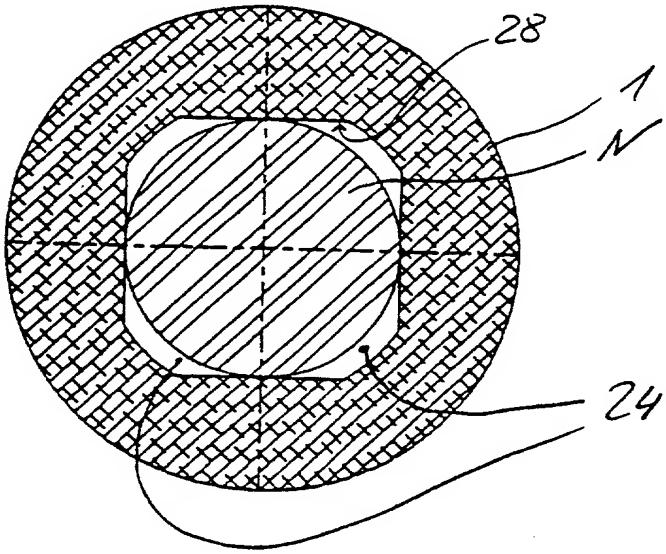


Fig. 3c



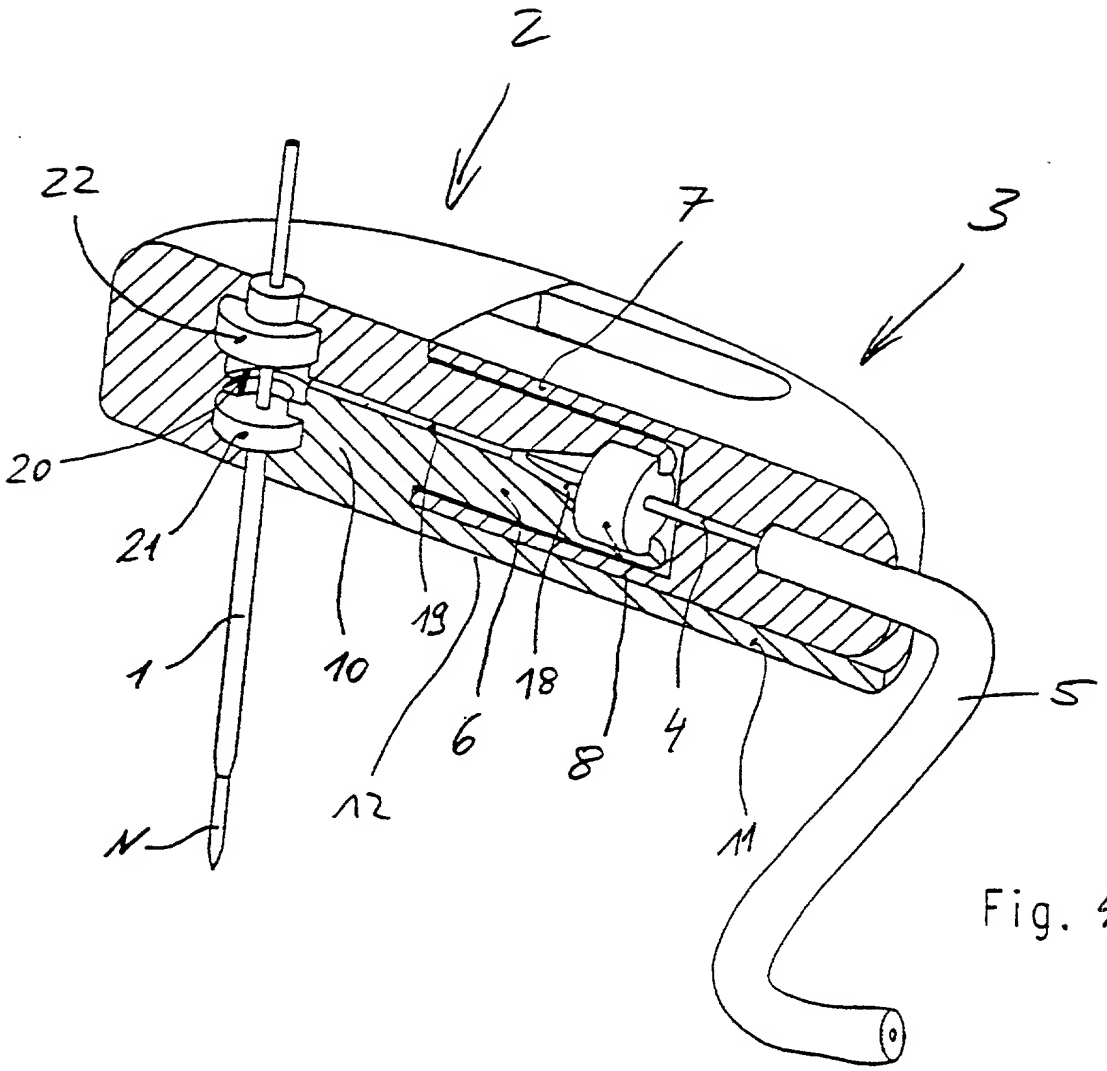


Fig. 4

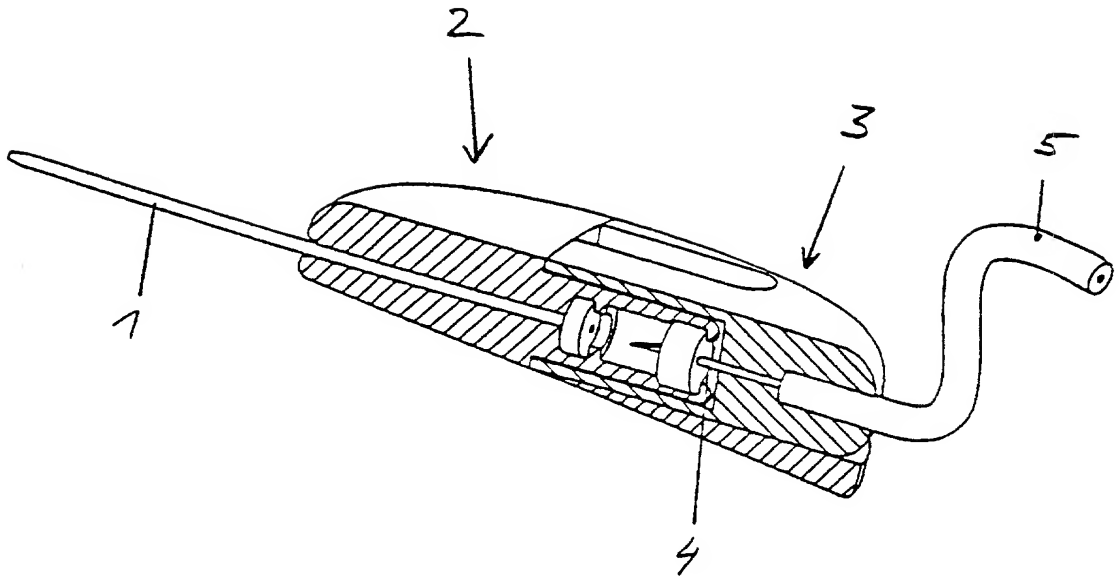


Fig. 5

Docket No. 14158

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Fritz Kirchhofer	
Appln. No. : Unknown	
Filed : Herewith	Group Art Unit: Unknown
Title : Cannula/Needle Combination for Subcutaneous Administration of an Active Surface	Examiner: Unknown

DECLARATION FOR UTILITY PATENT APPLICATION (37 C.F.R. § 1.63)

As a below named inventor, I hereby declare that my mailing address and citizenship are as stated below.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled:

Cannula/Needle for Subcutaneous Administration of an Active Substance

the specification of which:

☒ is attached hereto OR

☐ was filed on as United States Application Number or PCT International Application Number and amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information known to me that is material to patentability as defined in 37 C.F.R. 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? Yes	No
DE 19922 350 C1	Germany	05/14/1999	☐	☐	☒
WO 00/69493	PCT	05/01/2000	☐	☐	☒
			☐	☐	☐

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

PLEASE DIRECT ALL CORRESPONDENCE TO:

The address associated with **Customer Number: 25763**, currently:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Sole or First Inventor:

Given Name (First and middle)	Family Name or Surname	
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Inventor's Signature		Date: 8.11.01
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Second Inventor:

Given Name (First and middle)	Family Name or Surname	
Jürg	**Steck**	
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